

REMARKS

Claims 73-91 and 94-100 were pending in the present application. By this Amendment, Applicants have amended claims 73 and 95. Support for the claim amendments can be found in the specification and claims as originally filed. The present Amendment does not introduce any new matter, and thus, its entry is respectfully requested. Upon entry of the present Amendment, claims 73-91 and 94-100, as amended, will remain pending and under examination.

November 1, 2005 Office Action

Examiner's Claim Rejections Under 35 U.S.C. § 112 withdrawn

The Examiner withdrew the previous rejection of claims 73-91 and 94-100 under 35 U.S.C. §112, first paragraph.

In response, Applicants acknowledge and appreciate the withdrawal of this rejection.

Examiner's Claim Rejections Under 35 U.S.C. § 103

The Examiner maintained the previously set forth rejections of the claims as obvious under 35 U.S.C. §103 in light of various references already of record. The Examiner continued to contend that re-using a crystal after having obtained a positive result in a test renders obvious a crystal's reuse after a negative test result. Specifically, the Examiner has taken the position that because the art teaches re-use of crystals after a *positive* result is obtained, the re-use being possible after merely a washing step to disrupt the antigen-antibody complex on the surface, one

of ordinary skill in the art would readily recognize that reuse after a *negative* result would be obvious, even though no such specific teaching is found in the art of record.

The Examiner also asserted that the claims as amended in the previous Office Action do not exclude the inclusion of a washing step, even though such a step would not be necessary in conducting the claimed assay. Finally, the Examiner has indicated that the Applicants' forthcoming Declaration would not be considered because it was not submitted before the present Action was mailed. In that regard, Applicants refer to the October 27, 2005 telephone conference between the Applicants' undersigned attorney and Examiner Lucas in which the Examiner indicated that he would in fact consider a Declaration submitted in the response to the Final Office Action (of which Applicants' attorney was not yet aware and which had not yet been mailed out by the Office at the time of the telephone conference). Applicants appreciate the Examiner's willingness to consider the Declaration, which is attached to this Amendment.

In response to the rejections, without conceding the correctness of the Examiner's position, but to expedite allowance of the subject application, Applicants have amended the claims to clarify the exclusion of a washing step. Applicants' claimed invention is directed to, *inter alia*, a method for performing an immunodiagnostic test for a veterinary disease in an animal, the method comprising:

- a) measuring a resonant frequency of a piezoelectric (Pz) crystal comprising an electrode on which crystal is immobilized an antigen from an infectious agent associated with the veterinary disease, or an antibody specific for an antigen from said infectious agent;

b) contacting said crystal with a biological specimen from said animal to be tested, wherein said Pz crystal was previously used in a test on a different biological specimen which was negative for said infectious agent and wherein said contacting occurs without a prior washing step following the negative test;

c) measuring a resonant frequency of said crystal following step (b);

d) comparing the resonant frequency measured in step (a) with the resonant frequency measured in step c) wherein if the difference between the two frequencies is equal to or greater than a cut-off threshold value then said biological specimen is positive for the presence of said infectious agent.

Applicants reiterate that the invention as claimed is not rendered obvious by the various references cited by the Examiner. Applicants again point out that at least the feature allowing for re-use of the crystal following a negative test result is not taught or suggested in any of the art thus far cited by the Examiner, and thus, the claims, as amended, are not obvious over the art of record.

Applicants have attached hereto a Rule 132 Declaration executed by Dr. Yap Him-Hoo, supporting Applicants' assertion that one of ordinary skill in the art would not find such re-use after a negative result to be obvious in light of either the cited references, the general knowledge in the art, or a combination thereof¹. Such re-use after obtaining a negative result, without

¹In addition to the Declaration, Applicants attach hereto a copy of a brief article from the University of California-Davis referring to Dr. Yap and his work, a newspaper report quoting Dr. Yap following the lifting of the ban on chicken and egg imports from Malaysia, and excerpts

additional washing steps of the type required to decontaminate a crystal following a *positive* result, would not be reasonably expected to be successful. Dr. Yap is currently Head of the Animal, Meat & Seafood Regulatory Branch of the Food and Veterinary Administration of the Agri-Food & Veterinary Authority of Singapore (AVA). As stated in the Declaration, Dr. Yap's division is involved in daily testing for the detection of pathogens in livestock and plays a key role in protecting public health by insuring that Singapore's food supply is safe. The various testing techniques his division employs include isolation and plating out the bacteria for phage detection, Elisa detection, and glutamation on slides using antigens for the detection of antibodies. In Dr. Yap's opinion, based on his technical background and experience as a veterinarian, his important role in the daily testing of the food supply in Singapore, and his knowledge of the specific aspects of field testing for pathogens that could potentially enter the food supply, one would not have expected re-use of a sensor such as that employed in the present methods to be successful without a prior washing step following a negative test result. This view is in fact consistent with the teachings in the art of record. Nothing in the art suggests that such a technique, without the wash step, could be successfully employed. Because neither the art of record, nor the general knowledge in the relevant art suggests such a use, the art necessarily fails to appreciate the advantages of the Applicants' claimed methods. In particular, the claimed methods allow for easy, rapid, on-the-spot re-use of the testing device, and thus provide greater

from the AVA website (www.ava.gov.sg), describing various aspects of the work performed in the interest of protecting the food supply.

suitability for field use and a potential to cut down on the number of samples taken off site for laboratory testing. This convenient field use advantage, not associated with prior art methods, will save costs and increase food safety. Clearly, the cited art, either alone or in combination, simply does not appreciate a link, as the inventors have, between reusability of the Pz sensor after coming in contact with a negative sample and the advantages of such a reusable sensor for veterinary applications.

For at least the foregoing reasons, Applicants' claimed invention is not rendered obvious over the art cited by the Examiner. Applicants therefore believe that the amendments presented herein, further supported by the remarks and Rule 132 Declaration by Dr. Yap, fully overcome the Examiner's concerns. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. §103.

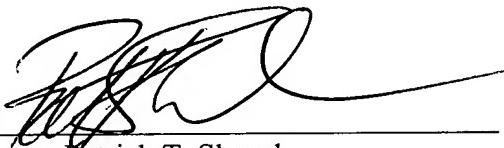
U.S. Application No. 10/019,676
Response to Final Office Action of November 1, 2005
Amendment dated April 3, 2006

In view of the above remarks and claim amendments, Applicants believe that the Examiner's rejections set forth in the November 1, 2005 Final Office Action have been fully addressed and that the present claims fully satisfy the patent statutes. Applicants therefore believe that the application is in condition for allowance. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

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By: _____



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Attachments: Rule 132 Declaration of Yap Him-Hoo
Copy of UC Davis newsletter excerpt
Copy of newspaper report
Excerpt from AVA website

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